

IN THE UNITED STATES DESIGNATED/ELECTED OFFICE

International Application No. : PCT/EP2003/010404
 International Filing Date : September 18, 2003
 Priority Date(s) Claimed : September 18, 2002
 Applicant(s) (DO/EO/US) : Thorsten HEINZEL et al.

Title: THE USE OF MOLECULAR MARKERS FOR THE PRECLINICAL AND
 CLINICAL PROFILING OF INHIBITORS OF ENZYMES HAVING HISTONE
 DEACETYLASE ACTIVITY

INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR §§ 1.56, 1.97 and 1.98

Commissioner for Patents
 P.O. Box 1450
 Alexandria, VA 22313-1450

Sir:

This information disclosure statement is made in accordance with 37 C.F.R. §§ 1.56, 1.97 and 1.98 as follows:

Timing and Fees

- ☒ Under 37 C.F.R. § 1.97(b), no fee or statement is required for filing this information disclosure statement is filed:
- ☐ within three months of the filing date of a national application other than a CPA under § 1.53(d);
 - ☐ within three months of the actual filing date of the national phase of a PCT application; OR
 - ☒ before the mailing of a first substantive office action (including after filing of an RCE).
- ☐ Under 37 C.F.R. § 1.97(c), this information disclosure statement is filed after the periods specified in 37 C.F.R. § 1.97(b), but before the mailing date of:
- a final rejection under 37 C.F.R. 1.113;
 - termination of prosecution, e.g. Ex Parte Quayle, M.P.E.P § 609(B)(2); OR
 - a notice of allowance under 37 C.F.R. § 1.311; and

is accompanied by:

- ☐ the statement as specified in 37 C.F.R. § 1.97(e) set out below; OR
- ☐ a check covering the fee of \$180.00 under 37 C.F.R. § 1.17(p).
- ☐ Under 37 C.F.R. § 1.97(d), this information disclosure statement is filed after the mailing date of the following actions which have not been withdrawn:
 - ☐ a final action under 37 C.F.R. § 1.113;
 - ☐ termination of prosecution, e.g. Ex Parte Quayle, M.P.E.P § 609(B)(2);
 - ☐ OR a notice of allowance under 37 C.F.R. § 1.311;

AND is filed on or before payment of the issue fee; AND is accompanied by:

the statement as specified in 37 C.F.R. § 1.97(e) as set forth below, and the fee of \$180.00 under 37 C.F.R. § 1.17(p).

Statements Under 37 C.F.R. 1.97(e)

- ☐ Each item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application having a mailing date not more than three months prior to the filing date of this information disclosure statement; or
- ☐ No item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and to the knowledge of the undersigned attorney after making reasonable inquiry, no item of information contained in this information disclosure statement was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing date of the information disclosure statement.

Cited Materials

- ☐ Copies of materials listed but not attached were cited in benefit (35 U.S.C. § 120) ancestor application Serial No. _____, on Form 892 by the Examiner and/or Form 1449 by the applicant; see 37 C.F.R. § 1.98(d).
- ☒ Copies of materials listed but not attached were cited in an international search report dated February 20, 2003.
- ☐ Not required by 37 CFR § 1.98.
- ☐ Copies of the materials listed are attached (except for the foregoing).

Non-English Language References

☒ An English-language search report or equivalent paper from a foreign patent office is provided indicating the relevance of the cited reference(s).

☐ A foreign-language search report from a foreign patent office is provided, and pertinent parts are translated substantively below:

X = document of particular relevance when it is taken alone

Y = document of particular relevance when it is combined with another such document

A = document defining the general state of the art

O = non-written disclosure

P = intercalated document

T = document cited to understand the theory or principle underlying the invention

E = patent document which has the benefit of a date earlier than the filing date and which was published only on or after this filing date

D = cited in the application

L = cited for another reason

& = publication of member of same patent family

☐ Translation of other relevant information on foreign search report

[insert necessary translation here]

Other Information


Payment of Fees Due (If Any):

☐ A check for \$_____ covering the fee identified above is attached.

☐ Please charge to Deposit Account No. 13-3402 \$_____ for the fee identified above.

☒ The Commissioner is hereby authorized to charge or credit any overpayment to Deposit Account #13-3402, two copies of this paper are attached for this purpose.

Respectfully submitted,



Anthony J. Zelano, Reg. No. 27,969
Attorney for Applicants

MILLEN, WHITE, ZELANO
& BRANIGAN, P.C.
Arlington Courthouse Plaza I
2200 Clarendon Blvd. Suite 1400
Arlington, Virginia 22201
Telephone: (703) 243-6333
Facsimile: (703) 243-6410

Attorney Docket No.: LEDER-15

Date: March 15, 2005

AJZ:aap

K:\LEDER\15\Information Disclosure Statement.doc

Please type a plus sign (+) inside this box →



PTO/SB/08A (08-00)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet

1

of

2

Complete if Known

10/528104

Application Number

Unassigned

Filing Date

March 16, 2005

First Named Inventor

Thorsten HEINZEL et al.

Group Art Unit

Unassigned

Examiner Name

Unassigned

Attorney Docket Number

LEDER-15

U.S. PATENT DOCUMENTS

Examiner Initials *	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
		Number	Kind Code ² (if known)		

FOREIGN PATENT DOCUMENTS

Examiner Initials *	Cite No. ¹	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Office ³	Number ⁴	Kind Code ⁵ (if known)				
	1	WO	9735990		Jamison Timothy F	October 2, 1997		
	2	EP	1050581		Medical & Biolog Lab Co LTD	November 8, 2000		
	3	WO	0071703		Methylgene INC.	November 30, 2000		

Examiner
Signature

Date

Considered

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached. Number refers to English language corresponding family member.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

10/528104

DT Rec'd PCT/PTO 16 MAR 2005

Please type a plus sign (+) inside this box



PTO/SB/08A (08-00)

Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 2 of 2

Complete if Known

Application Number	Unassigned
Filing Date	March 16, 2005
First Named Inventor	Thorsten HEINZEL et al.
Group Art Unit	Unassigned
Examiner Name	Unassigned
Attorney Docket Number	LEDER-15

NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	4	SU G H et al: "A NOVEL HISTONE DEACETYLASE INHIBITOR IDENTIFIED BY HIGH-THROUGHPUTTRANSCRIPTIONAL SCREENING OF A COMPOUND LIBRARY" CANCER RESEARCH, AMERICAN ASSOCIATION FO RCANCER REASEARCH, BALTIMORE, MD, US vol. 60, no. 12, 15 June 2000 pages 3137-3142, XP000985980	
	5	KWON H J et al: "A HISTONE DEACETYLASE INHIBITOR, TRICHOSTATIN A , INDUCES APOPTOSIS THROUGH SUPPRESSION OF ANTI-APOPTOTIC FACTORS, C-IAP-1 AND C-IAP-2 IN HUMAN PROTSTATE EPITHELIAL CELLS" PROCEEDINGS OF THE ANNUAL MEETING OF THE AMERICAN ASSOCIATION FOR CANCER RESEARCH, NEW YORK, NY, US vol. 40, March 1999, pages 581 XP002180771	
	6	SCHMIDT K ET AL: "INHIBITORS OF HISTONE DEACETYLASE SUPPRESS THE GROWTH OF MCF-7 BREAST CANCER CELLS" ARCHIV DER PHARMAZIE, VCH VERLAGSGESELLSCHAFT MBH, WEINHEIM, DE vol. 332, no. 10, 1999, pages 353-357, XP000985303	
	7	WARELL R P ET AL: "THERAPEUTIC TARGETING OF TRANSCRIPTION IN ACUTE PROMYELOCYTIC LEUKEMIA BY USE OF AN INHIBITOR OF HISTON DEACETYLASE" JOURNAL OF THE NATIONAL CANCER INSTITUTE, US DEPT, OF HEALTH, EDICATION AND WELFARE, PUBLIC HEALTH, US, vol. 90, no. 21, November 1998 pages 1621-1625, XP002928827	
	8	JUNG M: "INHIBITORS OF HISTONE DEACETYLASE AS NEW ANTICANCER AGENTS" CURRENT MEDICINAL CHEMISTRY, BENTHAM SCIENCE PUBLISHERS BV, BE vol. 8, 2001, pages 1505-1511, XP001098704	
	9	GREENBERG V L ET AL: "HISTONE DEACETYLASE INHIBITORS PROMOTE APOPTOSIS AND DIFFERENTIAL CELL CYCLE ARREST IN ANAPLASTIC THYROID CANCER CELLS" THYROID, MARY ANN LIEBERT, NEW YORK, NY, US, vol. 11, no. 4 April 2001 pages 315-325, XP009003316	
	10	"SMALL MOLECULE INHIBITORS OF HISTONE DEACETYLASE" EXPERT OPINION ON THERAPEUTIC PATENTS, ASHLEY PUBLICATIONS, GB, vol. 12, no. 6, 2002, pages 943-947, XP001120539	

Examiner
SignatureDate
Considered

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450.